

REMARKS

Double Patenting

Claims 1-3, 6, 7, 10-16, and 20-22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent 6,719,716. Pursuant to 37 C.F.R. 1.321(c), a terminal disclaimer may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application.

In accordance with 37 C.F.R. 1.321(c), Applicant encloses herewith a Terminal Disclaimer as signed by Applicant and the required fee. Accordingly, Applicant submits that this terminal disclaimer obviates the double patenting rejection.

Claims Rejection - 35 U.S.C. §103

Claims 1-8, 10-17, and 19-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication Number 2002/0082669 to Nitsch (the "Nitsch Application")<sup>1</sup> in view of U.S. Patent 6,951,548 to Einstein (the "Einstein Patent"). Applicant respectfully disagrees.

The Examiner argues that, with respect to independent Claims 1 and 13, the Nitsch Application teaches various limitations of these claims.

As evidenced by the Section 1.131 Affidavit of Robert E. Clark, attached hereto and incorporated herein by reference, Applicant reduced the teachings of these claim limitations to practice (i.e., the limitations in Claims 1 and 13 argued by the Examiner to be disclosed in the Nitsch Application) at least as early as July 18, 2000.

Applicant further described and/or claimed these above teachings in:

- (a) U.S. Provisional Patent Application, Serial Number 60/312,412, filed August 15, 2001 by Applicant;
- (b) U.S. Non-Provisional Patent Application, Serial Number 10/219,656, filed August 14, 2002, issued as U.S. Patent 6,719,716 to Applicant ('716 Patent); and
- (c) U.S. Continuation-In-Part Patent Application, Serial Number 10/769,483, filed January 30, 2004.

Since Applicant's actual reduction to practice of these teachings occurred prior to the publication date of the Nitsch Application (i.e., June 27, 2002) and prior to the filing date of the Nitsch Application (i.e., December 21, 2000), the Nitsch Application is not prior art to the teachings of Applicant's invention and shall neither bar the grant of a patent to Applicant nor bar the confirmation of the patentability of Claims 1 and 13.

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<sup>1</sup> The Nitsch Application was abandoned and never issued into a patent.

Application No.: 10/769,483  
Amendment, dated April 24, 2007

As set forth in Ex Parte Clapp, 227 U.S.P.Q. 972 (1985) and In Re Geiger, 2 U.S.P.Q.2d 1276 (CAFC 1987), in order to support a conclusion that the claimed combination is directed to obvious subject matter, the combination must be taught by the references themselves. It is well settled that the combination of references is not obvious under 35 U.S.C. §103, unless the prior arts contain the teaching of the combination. Absent the disclosures of the Nitsch Patent Application, there is clearly no disclosure, solely in the Einstein Patent, which teaches, suggests, or provides the motivation for the combination of elements found in Claims 1 and 13.

Accordingly, Applicant submits that independent Claims 1 and 13, as previously amended, presents allowable subject matter.

As Claims 2-8 and 10-12 depend from independent Claim 1 which, as previously amended, presents allowable subject matter, Claims 2-8 and 10-12 likewise present allowable subject matter.

As Claims 14-17 and 19 depend from independent Claim 13 which, as previously amended, presents allowable subject matter, Claims 14-17 and 19 likewise present allowable subject matter.

With respect to independent Claims 20 and 22, the Examiner argues that “it would be obvious to one of ordinary skill in the art to utilize the [conventional] pump taught in the Einstein Patent to reverse the directional flow of the fluid to pass back through the same cuvette 200, thereby irradiating the first irradiated fluid as it again passes the plurality of ultraviolet light sources 40 a second time to produce a second irradiated fluid in order to return treated blood back to the patient to provide the benefit of such treatment to said patient.”

Applicant respectfully disagrees. *First*, the teaching of Einstein Patent teaches away from Applicant’s invention and reversing the directional flow of the fluid to irradiate the blood a second time using the same cuvettes. The Einstein Patent discloses that “[t]he untreated blood will preferably flow through the irradiating chamber 20 for treatment via tubing structure 50 and cuvettes 200, 300 and exit to the treated blood storage tank 62 for storage after ultraviolet light exposure.” [Col. 4, Lines 63-64]. Since the treated blood is specifically to be stored in a treated blood storage tank, the Einstein Patent clearly does not disclose or teach the ability to reverse the directional flow and then irradiate this blood a second time using the same cuvettes. In fact, the Einstein Patent expressly states otherwise. Thus, as the treated blood is expressly disclosed to be “stored” in the tank, the Einstein Patent specifically teaches away from Applicant’s invention since the treated blood is to remain in the tank after passing through the apparatus.

*Second*, the suggestion of the Examiner of reversing the directional flow of the fluid in the blood irradiating apparatus of the Einstein Patent and irradiate the blood a second time using the same cuvettes appears to constitute an inoperable structure. The Einstein Patent makes the following discloses:

“[T]he blood irradiating apparatus 10 of the present invention will include at least one cascade-flow cuvette 300” [Col. 5, Lines 40-1] and “[t]he untreated blood will preferably flow through the irradiating chamber 20 for treatment via ... cuvettes 200, 300” [Col. 4, Lines

65-6].

“The cascade-flow cuvette 300 of the present invention includes a generally cylindrical housing 305 enclosing a flow passageway therein and having a front side 315 and a rear side 325 as shown. The cascade-flow cuvette 300 preferably includes an inlet 310 disposed near the top end of the housing 305 and an outlet 312 disposed near the bottom end of the housing 305 as shown. A number of steps 320 are preferably disposed within the cascade-flow cuvette 300 in order to cause a sufficiently turbulent flow of blood. In the preferred embodiment, the smallest sized step 320 will be located near the top end of the housing 305 of the cuvette 300 with the size of the steps 320 gradually increasing towards the bottom end of the cuvette 300 as best illustrated in the cross-sectional view of FIG. 6 taken along line 6--6 of FIG. 5.” [Col. 5, Lines 45-59].

“The stepped configuration of the cascade-flow cuvette 300 of the present invention assists in optimizing exposure of the blood to ultraviolet irradiation during treatment. As shown in the figures, the steps 320 of the cascade-flow cuvette 300 of the present invention will be configured with a number of apertures 330 disposed therein. The apertures 330 in the steps 320 of the cascade-flow cuvette 300 will permit a quantity of blood to flow from a higher step 320 to a lower step 320 of the cascade-flow cuvette 300 providing a sufficient degree of turbulence to optimize exposure of the blood to ultraviolet irradiation as previously discussed.” [Col. 5, Lines 60-67; Col. 6, Lines 1-3].

As disclosed in the Einstein Patent, during a part of a treatment, the untreated blood must pass through an inlet at the top of a cuvette, then, while inside the cuvette, pass downward over a number of steps that are designed to continually increase in size for impeding or causing turbulence in the flow of the blood, and then exit the outlet at the bottom of the cuvette and into the tank for storage. The suggestion by the Examiner that the flow of the blood in the apparatus in Einstein Patent can be reversed and treated a second time means that the following must occur. The blood would have to be pulled back out of the tank, pulled back through the outlet and into the bottom of the cuvette, then be pulled over or through all of the steps within the cuvette which will act as barriers against the flow of the blood, and while overcoming all of these steps, the blood must also simultaneously be pulled upward against and overcome the force of gravity, and then, for any blood that overcomes these obstacles, if any, the blood is then pulled back through the inlet at the top of the cuvette. The Examiner further indicates that all of this can be accomplished using the conventional pump disclosed in the Einstein Patent. Based on the foregoing, Applicant submits that such a structure is not inoperable.

*Lastly*, Applicant asserts that the Examiner’s position is provided in light of Applicant’s disclosure and that the Examiner is relying upon hindsight in proposing that the device in the Einstein Patent can be modified to provide the reverse directional flow and second irradiation of fluid using the same channel. With knowledge of Applicant’s device, Applicant’s invention appears obvious to the Examiner. However, but for the Examiner’s knowledge of Applicant’s device, the modification of the device in the Einstein Patent would not have occurred to the Examiner. Applicant’s assertion is further supported by the fact that those skilled in the art have not combined

Application No.: 10/769,483  
Amendment, dated April 24, 2007

the reverse directional flow and second irradiation of fluid with the device in the Einstein Patent to design Applicant's device. Thus, the proposed combination cited by the Examiner is predicated upon the Examiner's knowledge of Applicant's device and is not obvious to a person of ordinary skill in the art.

Based on the foregoing, there is no teaching, suggestion, or motivation in the Einstein Patent of the combination as suggested by the Examiner and it would not have been obvious to one of ordinary skill in the art to modify the Einstein Patent as suggested by the Examiner to create the combination of elements found in Claims 20 and 22.

Accordingly, Applicant submits that independent Claims 20 and 22 present allowable subject matter. Furthermore, as Claim 21 depends from independent Claim 20 which, presents allowable subject matter, Claim 21 likewise presents allowable subject matter.

Applicant submits that the application is now in condition for allowance and respectfully requests the Examiner to take such action.

If the Examiner believes that a telephone interview with Applicant's attorney would be beneficial, please do not hesitate to contact the undersigned.

Respectfully submitted,

By: 

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